

AMENDMENTS TO THE DRAWINGS:

The attached two (2) sheets of drawings includes new Figures 9 and 10. No new matter has been added.

Attachment: Two (2) New Sheets

REMARKS

I. Introduction

With the cancellation herein without prejudice of claims 4 and 17, claims 1 to 3, 5 to 16, and 18 to 45 are pending in the present application. In view of the foregoing amendments and the following remarks, it is respectfully submitted that all of the presently pending claims are allowable, and reconsideration is respectfully requested.

Applicants note with appreciation the acknowledgment of the claim for foreign priority and the indication that all certified copies of the priority documents have been received.

Applicants thank the Examiner for considering the previously filed Information Disclosure Statement, PTO-1449 paper and cited references.

II. Objection to the Drawings

The drawings were objected to for under 37 C.F.R. § 1.83(a). In this regard, two (2) new drawing sheets are submitted herewith. The Specification has been amended herein without prejudice to accord with the amended drawings. It is respectfully submitted that new Figures 9 and 10 obviate the present objection. Accordingly, withdrawal of this objection is respectfully requested.

III. Rejection of Claims 17 to 26 and 40 to 45 Under 35 U.S.C. § 112, First Paragraph

Claims 17 to 26 and 40 to 45 were rejected under 35 U.S.C. § 112, first paragraph as failing to comply with the written description requirement.

As an initial matter, claim 17 has been canceled herein without prejudice, thereby rendering moot the present rejection with regard to claim 17.

As regards claims 18 to 26 and 40 to 45, Applicants respectfully submit that the Specification as originally filed adequately describes the reservoir that holds the beneficial or edible material to one of ordinary skill in the art. For example, page 22, lines 1 to 6 of the Specification teaches that different types of therapeutic material may be stored in a chamber defined by elements 53, 55, and 57. Notwithstanding the foregoing, Figures 9 and 10 have been added herein without prejudice (and the Specification has been amended herein without prejudice to accord therewith) to even more readily illustrate the aforementioned features.

Moreover, it is respectfully submitted that it is well known to those skilled in the art how material is delivered by temperature activated means, moisture activated means, timed release means, and control means. Further, an aspect of the present invention is that the device for separating between the upper and lower jaws comprises a chamber from which beneficial or edible material may be delivered to a subject by, e.g., any one of the means recited in claim 18 or in claims 41 to 45.

In view of the foregoing, withdrawal of this rejection is respectfully requested.

IV. Rejection of Claims 1 to 5, 7, 14 to 16, 27 to 31, 33 to 37, and 39 Under 35 U.S.C. § 102(b)

Claims 1 to 5, 7, 14 to 16, 27 to 31, 33 to 37, and 39 were rejected under 35 U.S.C. § 102(b) as anticipated by U.S. Patent No. 4,898,535 ("Bergersen"). It is respectfully submitted that Bergersen does not anticipate these claims for at least the following reasons.

As an initial matter, claim 4 has been canceled herein without prejudice, thereby rendering moot the present rejection with regard to claim 4.

Claim 1 relates to a device for separating between the upper and lower jaws. As amended herein without prejudice, claim 1 recites that the device comprises two substantially U-shaped ribs and a deformable member attached at a posterior end of a pair of ribs on at least the lingual side thereof such that said member gradually changes its shape when a pressure is applied on said at least one nib by the jaws, wherein the yield strength of said ribs is significantly greater than that of said deformable member. Support for this amendment may be found, for example, at originally filed claim 4, which has been canceled herein without prejudice, and at page 12, lines 16 to 18 of the Specification.

Bergersen discloses a removable orthodontic appliance having upper and lower tooth receiving troughs 12 and 14, to prevent dislodging of the appliance during sleeping hours and to correct different severities of malocclusion. The troughs are separate at anterior ends 38 and 40, and are connected at posterior end 36 by a resilient hinge portion 34. In this regard Bergersen does not disclose, or even suggest, **a deformable member attached at a posterior end of a pair of ribs on at least the lingual side thereof such that said member gradually changes its shape when a pressure is applied on said at least one nib by the jaws**, as

recited in claim 1. In other words, Bergersen lacks a deformable member which is not a rib and which is attached at a posterior end of a pair of ribs on at least the lingual side thereof such that the member gradually changes its shape when a pressure is applied on the ribs by the jaws.

In the embodiments of Figures 1 to 3 of Bergersen, the appliance is molded as a single piece and the hinge portion is formed by making a slit along parting line 25. In the embodiments of Figures 4 and 5, a flexible metal plate 44 is inserted within the hinge area. In the embodiment of Figures 6 to 8, upper and lower trough parts 26A and 30A are formed by injection molding as separate elements which are interconnected by hinge portion 34A. Even if it were construed that a hinge portion 34 is a deformable member, the hinge portion is certainly not attached to the lingual side of a pair of ribs. This device is not adapted for use during an epileptic seizure. Since the device of Bergersen lacks a deformable member that connects the two ribs on the lingual side thereof, the two ribs when separated to a fullest extent during an epileptic seizure will not be returned to their original angular position upon cessation of the epileptic seizure, thereby causing discomfiture to the subject. Since the two ribs do not necessarily follow the movement of the jaws, the device of Bergersen may be separated from the teeth when the two ribs are separated to a fullest extent while the jaws are in the process of being closed, and may also be displaced by the tongue as it undergoes uncontrollable motions during an epileptic seizure.

Moreover, as the troughs and hinge portion are integrally formed in most embodiments, the yield strength of the troughs are intended to be substantially equal to that of the hinge portion. In contrast, amended claim 1 recites that the **yield strength of the ribs is significantly greater than that of the deformable member.**

Since the yield strength of the ribs of the embodiment described in claim 1 is significantly greater than that of the deformable member, the protection device is advantageously adapted to both bear the stress associated with increased interjaw compressive forces during an epileptic seizure by means of the relatively stiff ribs and to follow the movement of the jaws by means of the deformable member. The deformable member is sufficiently compressible to change shape following an application increased interjaw compressive forces, yet is sufficiently elastic to return to its original dimensions and configuration following the relaxation of the masticatory muscles.

In addition to being suitable for those that suffer from epilepsy when inserted by a subject within his mouth during the manifestation of an aura, the protection device of the present invention is also suitable for protecting a sport practitioner from externally afflicted injury, for suppressing the upper airway resistance syndrome, the sleep apnea syndrome, and snoring, form immobilizing the temporomandibular joint following jaw surgery to prevent permanent scarring, for physical therapy, and for providing relief to patients suffering from the myofascial pain disorder since the upper and lower jaws are ensured of being separated.

As indicated above, Bergersen does not disclose, or even suggest, all of the features recited in claim 1. As such, it is respectfully submitted that Bergersen does not anticipate claim 1.

Claims 2 to 5, 7, 14 to 16, 27 to 31, 33 to 37, and 39 ultimately depend from claim 1 and therefore include all of the features recited in claim 1. As such, it is respectfully submitted that Bergersen does not anticipate these dependent claims for at least the same reasons set forth above in support of the patentability of claim 1.

In view of all of the foregoing, withdrawal of this rejection is respectfully requested.

V. Rejection of Claims 16 and 29 Under 35 U.S.C. § 103(a)

Claims 16 and 29 were rejected under 35 U.S.C. § 103(a) as unpatentable over the combination of Bergersen and U.S. Patent No. 5,460,527 ("Kittelsen"). It is respectfully submitted that the combination of Bergersen and Kittelsen does not render unpatentable these claims for at least the following reasons.

Claims 16 and 29 ultimately depend from claim 1 and therefore include all of the features recited in claim 1. As more fully set forth above in support of the patentability of claim 1, Bergersen does not disclose, or even suggest, all of the features recited in claim 1. Kittelsen is not relied upon for disclosing or suggesting the features of claim 1 not disclosed or suggested by Bergersen. Indeed, Kittelsen does not disclose or suggest the features of claim 1 not disclosed or suggested by Bergersen.

In view of the foregoing, it is respectfully submitted that the combination of Bergersen and Kittelsen does not disclose, or even suggest, all of the features of the present claims. As such, it is respectfully submitted that the

combination of Bergersen and Kittelsen does not render unpatentable the present claims. Accordingly, withdrawal of this rejection is respectfully requested.

VI. Rejection of Claims 17, 24 to 26, and 40 to 44 Under 35 U.S.C. § 103(a)

Claims 17, 24 to 26, and 40 to 44 were rejected under 35 U.S.C. § 103(a) as unpatentable over the combination of Bergersen and U.S. Patent No. 6,244,269 ("Tyler"). It is respectfully submitted that the combination of Bergersen and Tyler does not render unpatentable these claims for at least the following reasons.

As an initial matter, claim 17 has been canceled herein without prejudice, thereby rendering moot the present rejection with regard to claim 17.

As indicated above, claim 1, from which claims 17, and 24 to 26 ultimately depend, relates to a device for separating between the upper and lower jaws and recites that the device comprises two substantially U-shaped ribs and a deformable member attached at a posterior end of a pair of ribs on at least the lingual side thereof such that said member gradually changes its shape when a pressure is applied on said at least one nib by the jaws, wherein the yield strength of said ribs is significantly greater than that of said deformable member.

Claim 40 relates to a method for delivering material to a subject. Claim 40, as amended herein without prejudice, recites the steps of:

- a) providing a device with two substantially U-shaped ribs, connected at least one end to one another, and a deformable member attached at a posterior end of a pair of ribs on at least the lingual side thereof, wherein the yield strength of said ribs is significantly greater than that of said deformable member and said deformable member is formed with at least one chamber suitable for housing a beneficial or edible material;
- b) filling each of said at least one chamber with a beneficial or edible material;
- c) inserting said device into the oral cavity of said subject such that said deformable member separates an upper set of posterior teeth from a corresponding lower set of posterior teeth; and
- d) allowing said beneficial or edible material to be delivered to said subject while said device follows the

movement of the jaws and said deformable member changes its shape.

Support for this amendment may be found, for example, at at originally filed claim 4 and at page 12, lines 16 to 18 of the Specification.

As indicated above in support of the patentability of claim 1, Bergersen does not disclose, or even suggest, **a deformable member attached at a posterior end of a pair of ribs on at least the lingual side thereof such that said member gradually changes its shape when a pressure is applied on said at least one nib by the jaws**, or ribs having a **yield strength significantly greater than that of the deformable member**. Claim 40 contains analogous features to claim 1 in this regard, and, as such, it is respectfully submitted that Bergersen does not disclose, or even suggest, all of the features recited in claim 40.

Tyler also does not disclose, or even suggest, the aforementioned features. In this regard, Tyler discloses a U-shaped mouthpiece formed from pliable flavored edible materials. The wearer clenching down customizes the fit of the mouthpiece therein and changes the sharp hard edges of the teeth to be soft and rounded. Tyler does not provide a mouthpiece with a chamber from which a beneficial or edible material can be delivered -- a flavored mouthpiece cannot be construed as being a chamber which houses beneficial or edible material. Moreover, since the upper and lower mouthpieces of Tyler are separate elements, a two piece mouthpiece of Tyler cannot follow the movement of the jaws while the deformable member changes its shape.

As indicated above, the combination of Bergersen and Tyler does not disclose, or even suggest, all of the features recited in any of claims 1 and 40. Claims 17 and 24 to 26, and 41 to 44 ultimately depend from claim 1, and therefore include all of the features recited in claim 1. Likewise, claims 41 to 44 depend from claim 40 and therefore include all of the features recited in claim 40.

In view of the foregoing, it is respectfully submitted that the combination of Bergersen and Tyler does not disclose, or even suggest, all of the features of the present claims. As such, it is respectfully submitted that the combination of Bergersen and Tyler does not render unpatentable the present claims. Accordingly, withdrawal of this rejection is respectfully requested.

VII. Rejection of Claims 18 to 21 and 45 Under 35 U.S.C. § 103(a)

Claims 18 to 21 and 45 were rejected under 35 U.S.C. § 103(a) as unpatentable over the combination of Bergersen, Tyler, and U.S. Patent No. 5,490,520 ("Schaefer et al."). It is respectfully submitted that the combination of Bergersen, Tyler, and Schaefer et al. does not render unpatentable these claims for at least the following reasons.

Claims 18 to 21 ultimately depend from claim 1 and therefore include all of the features recited in claim 1. As more fully set forth above, the combination of Bergersen and Tyler does not disclose, or even suggest, all of the features recited in claim 1. Schaefer et al. are not relied upon for disclosing or suggesting the features of claim 1 not disclosed or suggested by the combination of Bergersen and Tyler. Indeed, Schaefer et al. do not disclose or suggest the features of claim 1 not disclosed or suggested by the combination of Bergersen and Tyler.

Claim 45 depends from claim 40 and therefore include all of the features recited in claim 40. As more fully set forth above in support of the patentability of claim 40, the combination of Bergersen and Tyler does not disclose, or even suggest, all of the features recited in claim 40. Schaefer et al. are not relied upon for disclosing or suggesting the features of claim 40 not disclosed or suggested by the combination of Bergersen and Tyler. Indeed, Schaefer et al. do not disclose or suggest the features of claim 40 not disclosed or suggested by the combination of Bergersen and Tyler.

In view of the foregoing, it is respectfully submitted that the combination of Bergersen, Tyler, and Schaefer et al. does not disclose, or even suggest, all of the features of the present claims. As such, it is respectfully submitted that the combination of Bergersen, Tyler, and Schaefer et al. does not render unpatentable the present claims. Accordingly, withdrawal of this rejection is respectfully requested.

VIII. Rejection of Claim 23 Under 35 U.S.C. § 103(a)

Claim 23 was rejected under 35 U.S.C. § 103(a) as unpatentable over the combination of Bergersen, Tyler, and Kittelsen. It is respectfully submitted that the combination of Bergersen, Tyler, and Kittelsen does not render unpatentable claim 23 for at least the following reasons.

As indicated above, Bergersen, Tyler, and Kittelsen -- alone or in combination -- do not disclose, or even suggest, all of the features recited in claim 1. Claim 23 ultimately depends from claim 1, and therefore includes all of the features recited in claim 1. As such, it is respectfully submitted that the combination of Bergersen, Tyler, and Kittelsen does not render unpatentable claim 23 for at least the reasons more fully set forth above with regard to claim 1. Accordingly, withdrawal of this rejection is respectfully requested.

IX. Rejection of Claims 37 and 38 Under 35 U.S.C. § 103(a)

Claims 37 and 38 were rejected under 35 U.S.C. § 103(a) as unpatentable over the combination of Bergersen and U.S. Patent No. 5,323,787 ("Pratt"). It is respectfully submitted that the combination of Bergersen and Pratt does not render unpatentable these claims for at least the following reasons.

Claims 37 and 38 ultimately depend from claim 1 and therefore include all of the features recited in claim 1. As more fully set forth above in support of the patentability of claim 1, Bergersen does not disclose, or even suggest, all of the features recited in claim 1. Pratt is not relied upon for disclosing or suggesting the features of claim 1 not disclosed or suggested by Bergersen. Indeed, Pratt does not disclose or suggest the features of claim 1 not disclosed or suggested by Bergersen.

In view of the foregoing, it is respectfully submitted that the combination of Bergersen and Pratt does not disclose, or even suggest, all of the features of the present claims. As such, it is respectfully submitted that the combination of Bergersen and Pratt does not render unpatentable the present claims. Accordingly, withdrawal of this rejection is respectfully requested.

X. Allowable Subject Matter

Applicants note with appreciation the indication of allowable matter contained in claims 6 and 8 to 13. As regards the objection to these claims for depending from a rejected base claim, it is respectfully submitted that these claims are in condition for allowance for at least the reasons set forth above in support of the patentability of claim 1, from which claims 6 and 8 to 13 ultimately depend.

XI. Conclusion

It is therefore respectfully submitted that all of the presently pending claims are allowable. All issues raised by the Examiner having been addressed, an early and favorable action on the merits is earnestly solicited.

Respectfully submitted,

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Attachments